Financial Reporting in the Pharmaceutical Industry

by Robert Kirk

In this issue of Accountancy Plus I have taken the opportunity to investigate how accounting standards (both local and international) play a unique role in the financial statements of pharmaceutical companies. Clearly a number of the standards would apply equally to other industries but the following topics play a central role in this particular industry:

- **Research and development expenditure**
- **Research and development tax credits**
- **The valuation of inventories**
- **Product licencing and revenue recognition**

Research and development expenditure

Under international reporting, IAS 38 Intangible Assets, capitalisation of all development expenditure is compulsory from the point when it becomes probable that attributable economic benefits will be realised. The key issue has been what does probability mean? Superficially, the standard is clear, no expenditure may be capitalised for research, but one must be recognised for development, if six criteria are met. These are as follows:

- It is technically feasible to complete the intangible asset for use or sale;
- It is the entity's intention to complete the intangible asset for use or sale;
- The entity has the ability to use or sell the intangible asset;
- It can be demonstrated that it is probable that the intangible asset will generate future-economic benefits;
- The entity has adequate technical, financial and other resources to complete the development; and
- The entity can measure reliably the expenditure attributable to the intangible asset during its development.

The challenge has been trying to match these generic criteria with the actual processes and risks of pharmaceutical product development. In the United States a very prudent approach has been adopted and all research and development must be written off immediately as an expense.

Some of the key questions that arise include:

- Could costs be capitalised prior to obtaining first major market approval?
- Is there sufficient certainty at any point in the approval process to support an argument of probable future benefit?
- Does recognition have to be deferred until final approval has been obtained?

Given the strong market reactions to announcements of changes in the status and timing of regulatory approvals, there clearly is a risk discount built in by the market for development uncertainty until final approval and labelling is cleared.

What about costs incurred after first major market approval - is there now sufficient certainty of a product's commercial viability? There is no clear-cut answer. Different products will have different success in different markets and recent history has shown that gaining approval in one market is not a guarantee of approval elsewhere.

How is post launch expenditure to be accounted for? There is a strong argument that this is, in substance, marketing spend and thus should be expensed.

Although the capitalisation of development expenditure does increase the value of intangible assets and (short-term) profitability the industry at large usually assesses the uncertainties of getting a drug approved to be too great to justify capitalising significant development costs. An example of a typical accounting policy adopted for Irish pharmaceutical companies is illustrated by Trinity Biotech Plc as follows:

Trinity Biotech Plc

Notes to the consolidated financial statements December 31 2018

Basis of Preparation and Significant Accounting Policies (Extract)

Expenditure on development activities, whereby research findings are applied to a plan or design for the production of new or substantially improved products

and processes, is capitalised if the product or process is technically and commercially feasible and the Group has sufficient resources to complete the development. The expenditure capitalised includes the cost of materials, direct labour and attributable overheads and third-party costs. Subsequent expenditure on capitalised intangible assets is capitalised only when it increases the future economic benefits embodied in the specific asset to which it relates.

The technical feasibility of a new product is determined by a specific feasibility study undertaken at the first stage of any development project. The majority of our new product developments involve the transfer of existing product know-how to a new application. Since the technology is already proven in an existing product which is being used by customers, this facilitates the proving of the technical feasibility of that same technology in a new product.

The results of the feasibility study are reviewed by a design review committee comprising senior managers. The feasibility study occurs in the initial research phase of a project and costs in this phase are not capitalised.

The commercial feasibility of a new product is determined by preparing a discounted cash flow projection. This projection compares the discounted sales revenues for future periods with the relevant costs. As part of preparing the cash flow projection, the size of the relevant market is determined, feedback is sought from customers and the strength of the proposed new product is assessed against competitors' offerings. Once the technical and commercial feasibility has been established and the project has been approved for commencement, the project moves into the development phase.

All other development expenditure is expensed as incurred. Subsequent to initial recognition, the capitalised development expenditure is carried at cost less any accumulated amortisation and any accumulated impairment losses (Note 1(viii)).

Expenditure on research activities, undertaken with the prospect of gaining new scientific or technical knowledge and understanding, is recognised in the statement of operations as an expense as incurred.

Under the local standard, FRS 102, local companies have a clear choice as to whether or not to capitalise development expenditure using the same criteria as IAS 38 but again there is a reluctance to do so. Under the micro standard, FRS 105, all research and development must be expensed immediately so a micro pharmaceutical company may decide to opt for a higher level of reporting under FRS 102 if they wish to capitalise development costs.

Randox Laboratories Ltd in Northern Ireland and Aerogen Ltd in the Republic of Ireland are two companies that have opted to capitalise development costs under FRS 102:

Randox Laboratories Ltd

Notes to the financial statements year ended 31st December 2018

Accounting policies (Extract)

Intangible assets

Development expenditure:

Development expenditure relating to diagnostic products manufactured by the company is written off as incurred, except where the directors are satisfied as to the technical, commercial and financial viability of individual projects. In such cases, the identifiable expenditure is capitalised and amortised over the period in which the company is expected to benefit. This period is typically three years. Provision is made for any impairment.

Capitalised development costs include external direct costs of materials and services together with direct labour costs and overheads relating to development expenditure. Development costs that are directly attributable to the design and testing of identifiable and unique products controlled by the company are recognised as intangible assets when the following criteria are met:

- It is technically feasible to complete the product so that it will be available for use;
- Management intends to complete the product and use or sell it;
- There is an ability to use or sell the product;
- It can be demonstrated how the product will generate probable future economic benefits;
- Adequate technical, financial and other resources to complete the development and to use or sell the product are available; and
- The expenditure attributable to the product during its development can be reliably measured.

Other development costs that do not meet these criteria are recognised as an expense as incurred. Development costs previously recognised as an expense are not recognised as an asset in a subsequent period.

Aerogen Ltd

Year ended 31st December 2017

Notes

Significant accounting policies (Extract)

Intangible assets

Research and development (R&D)

Expenditure on research activities is recognised in the profit and loss account as an expense as incurred. R&D tax credits are credited to administrative expenses as earned.

Expenditure on development activities may be capitalised if the product or process is technically and commercially feasible and the company intends and has the technical ability and sufficient resources to complete development, future economic benefits are probable and if the company can measure reliably the expenditure attributable to the intangible asset during its development.

R&D tax credits

There is no accounting standard on the topic but it is generally agreed that it is appropriate to consider that under IFRS the R&D tax credit is, in substance, a government grant toward R&D expenditure (having regard to the government's expressed aim of reducing the economic cost of undertaking R&D activity in Ireland, and the method by which the amount of the relief is now determined), and, accordingly, it could be presented in the income statement as a pre-tax government grant.

However, a number of companies have chosen to record the tax credit as a reduction in the income tax charge for the year.

It is interesting to note that Aerogen Ltd have treated the tax credit as a reduction in administrative expenses (see above) rather than as a separate pre-tax income but they have also recorded grants on research and development as other income.

There are no accounting differences between companies reporting under IFRS or local accounting standards.

Other operating income

Other operating income		
	2017	**2016**
Government grants (market access and R&D)	108,908	175,390

There are no accounting differences between companies reporting under IFRS or local accounting standards.

The valuation of inventories

Similar to other manufacturing companies all costs required to bring the inventories to their precise location and condition should be included in their valuation. The key issue is which overheads to include and how much overhead.

Clearly all production overheads must be included but what other overheads? Having visited a number of large pharmaceutical manufacturing sites in England over the years I have been surprised that a number include accountants' salaries in their valuation on the grounds that everyone on the site is contributing to the manufacturing process and this seems to be acceptable to the auditors.

There is certainly a lot of judgment in deciding which overheads to include as well as deciding what the normal level of capacity is to absorb the overheads into the valuation. Most companies take the view their current budget is acceptable as long as it is not out of line with previous years.

Another issue is the problem of obsolescence and slow-moving inventory which must be reduced to their fair value less costs to sell (net realisable value) under both IAS 2 and FRS 102.

One company which had problems a number of years ago was the Elan Corporation Plc who had to write-

down €14million inventory when the drug Tysabri was withdrawn from the US market after a medical scare.

Elan Corporation Plc

Year ended 31st December 2005. Notes to the financial statements (Extract)

8. Inventory

Product inventories at December 31 of each year consisted of the following (in millions):

	2005	2004
	$	$
Raw materials	8.3	6.8
Work-in-process	9.7	8.2
Finished goods	7.3	14.0
Total inventory	**25.3**	**29**

During the year ended December 31, 2005, we recognised a write-down of finished goods of $14.0 million related to Tysabri, as a result of the voluntary suspension of the marketing and dosing in clinical trials of the product.

After further testing the drug re-entered the market under strict conditions of use two years later and although it is possible to reverse the write-down it was too late for the company as the drugs were by that time out of date.

Product licencing and revenue recognition

Increasingly, pharmaceutical companies are licensing development drugs or entering into collaboration agreements. The accounting is complex if it involves milestone payments, equity stakes or ongoing commitments such as shared R&D or manufacturing.

Under FRS 102, if an acquired product is in early stage development, the licence cost typically is written off - the upfront amounts tend to be small and likelihood of success considered too low to recognise the value as an asset. But practice for late stage licence-ins varies. Some pharmaceutical companies capitalise late stage licence costs while others choose to be vaguer.

Under IAS 38, intangibles that are acquired outside a business combination are assumed to be assets, and not an expense. IAS 38 effectively presumes that development risk is factored into the purchase price and an intangible asset should be recognised.

How about the more complex arrangements such as when a large pharmaceutical company takes a stake in a biotech to gain access to specific products or technologies?

It may appear that the company has acquired an equity investment which may be a financial asset or an associate, joint venture, or even a subsidiary. Is this really a purchase of R&D and should this amount be treated in whole or in part as an intangible asset? Questions include whether the entity is, in substance, a stand-alone enterprise, and whether it has the resources to continue on a going concern basis.

If the conclusion is that the arrangement is an investment, IFRS 9 requires equity investments to be carried at fair value, with changes in value recognised either directly in profit and loss or in other comprehensive income, if it is not held for trading.

And how about the revenue? A licensor needs to assess whether the licence is distinct or not. Accounting for a normal licence should be - straightforward if distinct - under IFRS 15 and FRS 102 royalties generally are recognised on a straight-line basis over the life of the agreement. But if not distinct, under IFRS 15, it will be combined with the manufacturing service as a single performance obligation.

Trinity Biotech Plc

Notes to the consolidated financial statements December 31, 2018

Basis of Preparation and Significant Accounting Policies

xvi) Revenue recognition (Extract)

The Group operates a licensed referenced laboratory in the US, which provides testing services to institutional customers and insurance companies. In the US, there are rules requiring all insurance companies to be billed the same amount per test. However, the amount that each insurance company pays for a particular test varies according to their own internal policies and this can typically be considerably less than the amount invoiced. We recognise lab services revenue for insurance companies by taking the invoiced amount and reducing it by an estimated percentage based on historical payment data. We review the percentage reduction annually based on the latest data.

As a practical expedient, and in accordance with IFRS, we apply a portfolio approach to the insurance companies as they have similar characteristics. We judge that the effect on the financial statements of using a portfolio approach for the insurance companies will not differ materially from applying IFRS 15 to the individual contracts within that portfolio.

Conclusion

Undoubtedly the pharmaceutical industry has a number of difficult accounting issues posed by the uncertainty that exists in the industry as to the success or failure of their research and development programme together with some complicated revenue relationships.

Robert Kirk

Robert Kirk, CPA, is professor of Financial Reporting at the University of Ulster. Robert is also author of the CPA Ireland Skillnet publication, A New Era for Irish and UK GAAP – A Quick Reference Guide to FRS 102.